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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/762,629	05/14/2001	Morten Jorsboe	9192.15USWO	6531

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EXAMINER	
KALLIS, RUSSELL	

ART UNIT	PAPER NUMBER
1638	12

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,629	JORSBOE ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 1/2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the inventions are united by the common technical feature of selecting transformed cells for galactose tolerance. Examiner has found Applicant's arguments persuasive and has rejoined Groups I-IV, cancelled claims 25-73, now claims 74-89.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74-89 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims polynucleotides encoding enzymes that enhance conversion of galactose to UDP-glucose.

Applicant describes enzymatic properties of a broad rage of enzymes involved in galactose metabolism on page 60, lines 5-15 by reference to enzyme classification numbers and gives the gene name for a UDP-glucose-dependent uridyl transferase from *E. coli* (*galT*).

Applicant does not describe the polynucleotides of any enzymes that enhance conversion of galactose to UDP-glucose.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Given the failure of the polynucleotides encoding enzymes that enhance conversion of galactose to UDP-glucose to be adequately described, methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-111.

Claims 74-89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transformation of potato and seed rape cells and tissue using the *E. coli galT* gene and selection for transformed plant material, does not reasonably provide enablement for transformation of all types of cells and tissues either from plants, animals or bacteria using the *E. coli galT* gene or transformation using any other polynucleotide encoding an enzyme that enhances conversion of galactose to UDP-glucose. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant claims a process of selecting for cells able to grow on galactose by transformation of said cells with polynucleotides encoding enzymes that metabolize galactose; galactokinase, UTP-dependent pyrophosphorylase, and UDP-glucose-dependent uridyl transferase; and transformed plants thereof.

Applicant teaches the toxicity of galactose to various plant species (Example 3 pages 54-60), transformation of potato and seed rape cells and tissue using the *E. coli galT* gene and selection for transformed potato and seed rape cells and tissue on galactose containing media (Examples 4 and 5).

Applicant does not teach transformation of all types of cells and tissues either from plants, animals or bacteria using the *E. coli galT* gene or transformation using any other polynucleotide encoding an enzyme that enhances conversion of galactose to UDP-glucose.

The screening for plants that escape the selection process is unpredictable and requires further experimentation to determine the best conditions of selection for each and every variety or species claimed and when the optimal time for selection should occur in order to recover transformed material. (Pasco-Gaunt S. *et al.* Journal of Experimental Botany; Vol. 52, No. 357; pp. 865-874 on page 873 column 1, 2nd full paragraph, the entire paragraph).

Moreover, when contemplating a range of enzymes from a metabolic pathway it is important to consider rate limiting steps that occur after the introduced enzymatic activity that would negate the desired selectable advantage. In the present example, UDP-glucose epimerase activity in *Arabidopsis* was not induced in the presence of galactose and its activity remained

low; and since it is downstream in the pathway of galactose metabolism from galactokinase and UDP-glucose uridylyltransferase, transformation with those upstream polynucleotides may not provide for galactose selection in a variety of plant species (Dormann P. *et al.*, The Plant Journal, 1998 March; Vol. 13 No. 5; pp. 641-652; See Abstract).

Given the lack of guidance for selecting cells or plants transformed with polynucleotides encoding enzymes that enhance the conversion of galactose to UDP-glucose, and given the breadth of the claims and the unpredictability in the art, undue trail and error experimentation would be needed by one skilled in the art to evaluate the efficiency of selection in a multitude of non-exemplified cell or plant species transformed with a multitude of galactose to UDP-glucose converting genes. Therefore, the invention is not enabled for the scope set forth in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 80-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 80-85, recite various avenues of presenting galactose to the cell that comprise placing in the selection media derivatives of galactose comprising the galactose molecule and precursors of galactose that require enzymatic conversion to galactose in the selection media. Thus, Claims 80-85 fail to further limit Claim 74.

Claim 75 depends from Claim 75. A claim cannot depend from itself but must depend from a preceding claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are indefinite as discussed supra.

Claims 74-75, 78-85 and 87-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Mollet B *et al.* (Journal of Bacteriology, July 1991; Vol. 173, No. 14; pp. 4464-4473). Mollet teaches transformation of galactose sensitive mutants of *E. coli* with genes from *Lactobacillus helveticus* coding for galactokinase (*galK*) and phosphate uridyl transferase (*galT*) and growth and selection for transformed cells that overcome the galactose toxicity (page 4466 column 2, 1st paragraph of the Results and page 4469 column 2, 1st paragraph of the Discussion).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 74-75, 78-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bojsen K. *et al.* (U.S. Patent 5,767,378 published June 16, 1998) in view of Mollet B *et al.* (Journal of Bacteriology, July 1991; Vol. 173, No. 14; pp. 4464-4473).

Applicant broadly claims a process of selecting for cells able to grow on galactose by transformation of said cells with polynucleotides encoding enzymes that metabolize galactose and transformed plants thereof.

Bojsen teaches transformation of cells from tobacco and sugar beet with cDNA encoding mannose and xylulose metabolizing enzymes selected for on mannose or xylulose containing medium (Examples 5-12, columns 10-13).

Bojsen does not teach transformation of cells with cDNA encoding galactose metabolizing enzymes selected for using galactose containing medium.

The teachings of Mollet are discussed supra.

It would have been obvious at the time of Applicant's invention to modify the invention of Bojsen to include galactose containing media and galactose metabolizing enzymes as taught by Mollet. One of skill in the art would have been motivated by the knowledge common in the art that selection for transformed plants without using herbicides or antibiotics are valuable materials for genetic engineering of plants and that with the success of Bojsen in transforming plants to grow on mannose and xylulose one would have had a reasonable expectation of success of utilizing polynucleotides encoding galactose metabolizing enzymes to select for transformed plants and plant cells.

Claims 76-77 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a process for selecting for a cell or tissue transformed with an isolated polynucleotide encoding a UTP-dependent pyrophosphorylase and a cell or tissue transformed with an isolated polynucleotides encoding a galactokinase, a UTP-glucose-dependent uridyl

transferase, and a UTP-dependent pyrophosphorylase wherein said transformed cells or tissue demonstrate the ability to grow on galactose selection media.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
February 4, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638